Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of analgesic effect of paracetamol versus pethidine in labor

Protocol summary

Study aim
Comparison of analgesic effect of paracetamol versus pethidine in labor

Design
In this interventional study, 100 pregnant women who are candidates for natural childbirth will be selected and divided into two groups using block randomization method (n=50 in each group). Proper counseling will be done and a written informed consent will be obtained before starting the treatment regimen.

Settings and conduct
Upon starting the active phase of labor intervention group1 will receive intravenous Paracetamol 1g/6.7 ml (CaspianTamin Co.) and 1 ml intramuscular placebo injectionin and intervention group 2 will receive intramuscular Pethidine 50 mg/1 ml (CaspianTamin Co.) and 6.7 ml intravenous placebo injection.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Over 37 weeks pregnancy, first or second pregnancy, singleton. Exclusion criteria: Malpresentation of fetus، macrosomia.

Intervention groups
Intervention group 1: Intravenous Paracetamol 1g /6.7 ml (CaspianTamin Co.) and 1 ml intramuscular placebo injection. Intervention group 2: Intramuscular Pethidine 50 mg/1 ml (CaspianTamin Co.) and 6.7 ml intravenous placebo injection.

Main outcome variables
pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150808023559N17**
Registration date: **2018-03-24, 1397/01/04**
Registration timing: **prospective**

Last update: **2018-03-24, 1397/01/04**
Update count: **0**

Registration date
2018-03-24, 1397/01/04

Registrant information

Name
Somaieh Matin

Name of organization / entity
Ardabil University of Medicine Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-19, 1397/01/30

Expected recruitment end date
2018-06-20, 1397/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of analgesic effect of paracetamol versus pethidine in labor

Public title
Labor pain relief with paracetamol and pethidine

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Over 37 weeks pregnancy First or second pregnancy Singleton

Exclusion criteria:
Malpresentation of fetus Macrosomia

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are assigned randomly by blocking in one of the two specified groups and after selecting the envelope for each patient, before starting the treatment regimen envelope will be opened and based on the protocol, one of two methods will be selected.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and clinical caregivers are not aware of the type of medication

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ardabil University of Medical Sciences

Street address
Ardabil University of Medicine Sciences, Daneshgah street, Ardabil

City
Ardabil

Province
Ardabil

Postal code
5615783134

Approval date
2017-12-31, 1396/10/10

Ethics committee reference number
IR.ARUMS.REC.1396.202

Health conditions studied

1

Description of health condition studied
Labor pain

ICD-10 code
O80, O84

ICD-10 code description
Delivery

Primary outcomes

1

Description
Pain

Timepoint
Before analgesic administrations and two times (30 and 60 min) after intervention

Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Apgar

Timepoint
1 and 5 minutes after birth

Method of measurement
Apgar test

Intervention groups

1

Description
Intervention group: Intravenous Paracetamol 1g /6.7 ml (CaspianTamin Co.) and 1 ml intramuscular placebo injection

Category
Treatment - Drugs

2

Description
Intervention group: Intramuscular Pethidine 50 mg/1 ml (CaspianTamin Co.) and 6.7 ml intravenous placebo injection

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alavi Hospital

Full name of responsible person
Farnaz Enamzade
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ardabil University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available